

Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-4 and 6-14 are pending in the application, with claim 1 being the independent claim. Claims 11-14 were previously withdrawn from consideration.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Miscellaneous

Applicants thank the Examiner for her reconsideration and withdrawal of the rejections under (1) 35 U.S.C. § 102, (2) 35 U.S.C. § 103(a) over Tullis and Goodchild, and (3) 35 U.S.C. § 103(a) over Tullis, Goodchild and Bennett.

Rejections under 35 U.S.C. § 103 in view of Hoffman

Claims 1, 2, 4, 6, 7, 9 and 10 were rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over U.S. Pat. No. 7,737,108 ("Hoffman"). Applicants respectfully traverse this rejection.

Based on the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) ("KSR"), and current USPTO Examination Guidelines, the proper objective analysis for determining obviousness under 35 U.S.C. § 103 is as stated in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) ("Graham"). Under this analysis, obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court include: (1) determining the scope and content

of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. Additionally, in order to be obvious over the cited documents, *KSR* provided that establishment of a *prima facie* case of obviousness requires the Examiner to provide an apparent reason to combine the claimed elements and a reasoned articulation that the combination of elements would have been known to produce a predictable result. In the present case, this burden has not been met.

Hoffman reports a membrane transporting composition which includes a membrane disrupting agent. The membrane disrupting agent is a hydrophobic polymer. See, e.g., col. 3, ll. 61. Optionally, the hydrophobic polymer can be coupled to a hydrophilic polymer. See, e.g., col. 4, ll. 1-2. Thus, if a hydrophilic polymer is present, it MUST be coupled to the hydrophobic polymer.

This is exemplified in Fig. 3, Example 2, and claim 1 of Hoffman. Specifically, in Fig. 3, PEG (i.e., the hydrophilic polymer) or drug is linked to the membrane-disruptive polymer backbone (i.e., hydrophobic polymer) via an acid degradable linker. In Example 2, a terpolymer of DMAEMA, BMA, and styrene benzaldehyde was used as a membrane -disruptive backbone, and the hydrophilic polymer, PEG, was linked to the terpolymer. In claim 1, the claim recited that the composition has the constitution in which hydrophobic component was linked to the hydrophilic component.

Since the composition of Hoffman requires a hydrophobic component as an essential component, and the hydrophilic component is an optional component (see, e.g., col. 6, ll. 11-19), then not only is the composition distinct, but the mechanism of action

between Hoffman and the claimed invention is different. Thus, one of skill in the art could not have looked to Hoffman and predicted the result of the present invention. Therefore, the *prima facie* case of obviousness has not been met.

At least for the above reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103.

Rejections under 35 U.S.C. § 103 in view of Hoffman and Tullis

Claims 1-4 and 6-10 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hoffman in further view of U.S. Pat. No. 4,904,582 ("Tullis"). Applicants respectfully traverse this rejection.

As described above, Hoffman does not teach or provide any reason for a conjugate comprising an oligonucleotide and a hydrophilic polymer, wherein the end of the oligonucleotide is covalently linked to the hydrophilic polymer via an acid-cleavable linkage. Tullis is provided by the Examiner allegedly as disclosing the c-myc gene. However, Tullis does not remedy any of the deficiencies of Hoffman. Namely, Tullis does not teach or provide any reason for a conjugate comprising an oligonucleotide and a hydrophilic polymer, wherein the end of the oligonucleotide is covalently linked to the hydrophilic polymer via an acid-cleavable linkage. Thus, the *prima facie* case of obviousness has not been established.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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